AD-A148 740 REVIEW OF THE US ARMY'S USE OF VOLUNTEERS IN RESEARCH EXPERIMENTS(U) GENERAL ACCOUNTING OFFICE WASHINGTON DC HUMAN RESOURCES DIV 06 NOV 84 GAO/HRD-85-17 1/1

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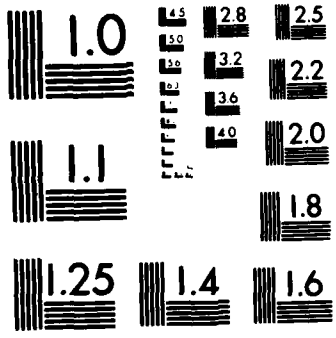

MICROCOPY RESOLUTION TEST CHART
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UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

HUMAN RESOURCES
DIVISION

NOVEMBER 6, 1984

B-216922

The Honorable Thomas J. Downey
House of Representatives

Dear Mr. Downey:

Subject: Review of the U.S. Army's Use of Volunteers in Research Experiments (GAO/HRD-85-17)

This is in response to your February 1984 request that we review the use of servicemen in U.S. Army research experiments. You expressed concern as to whether volunteers were fully informed of the nature of the experiments, the chemicals administered, and the potential adverse health effects. We discussed our observations with you on August 8, 1984. In accordance with your request, this report summarizes the issues we discussed concerning current and past Army procedures on the use of volunteers in research experiments.

The Army conducts research using human volunteers to maintain and protect the health of its personnel who may be exposed to a variety of diseases and combat conditions. Volunteers used in these research experiments are selected from civilian and military groups.

Our limited review indicated that the Army is attempting to more fully inform volunteers about the specific nature of research experiments in which they have agreed to participate than it did before 1975. In 1976, the Office of the Inspector General (OIG), Department of the Army, reported that information provided to volunteers participating in research experiments before 1975 was general in nature and did not provide details regarding the experiments.[1] Procedures have since been initiated

[1] Use of Volunteers in Chemical Agent Research, DAIG IN 21-75, March 10, 1976.

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requiring that all volunteers be fully informed of the research experiments. Current procedures also require that proposed experiments be reviewed at the local command and within the Office of the Army Surgeon General to assure the protection of the volunteers before research begins.

We conducted our review within the U.S. Army Medical Research and Development Command (USAMRDC) and at the Human Use Review Office (HURO), which are under the jurisdiction of the Army Surgeon General. USAMRDC has prime responsibility for research into the prevention and treatment of health hazards confronting Army personnel. HURO reviews Army medical department research experiments involving the use of volunteers.

As of May 1984, there were about 200 research experiments using volunteers within USAMRDC. We reviewed records for 50 of these experiments to determine if reviews of proposed research using volunteers occurred (see p. 6) and 104 of them to determine if the written explanations of proposed research indicated that volunteers would be informed (see p. 7). We met with the Assistant Deputy Commander, USAMRDC, and with the Chief, HURO, to discuss current Army procedures established to review research experiments using volunteers. We examined HURO computer listings of current Army research experiments using volunteers and reviewed HURO records of research proposals, annual research reports, and minutes of review meetings concerning proposed research to identify

--current research experiments using volunteers and

--Army procedures to inform and protect volunteers.

We also examined Army regulations established for the protection of volunteers in research experiments to determine current Army policies in this area. In addition, we visited two USAMRDC subordinate commands--the U.S. Army Institute of Surgical Research at Fort Sam Houston, Texas, and the U.S. Army Medical Research Institute of Infectious Diseases at Fort Detrick, Maryland--to discuss local command level review procedures with responsible officials. We also reviewed records of research experiments maintained at these subordinate commands.

We met with the Deputy Director, Division of Scientific Investigations, and other representatives of the Food and Drug Administration (FDA), in the Department of Health and Human Services (HHS), who were knowledgeable of Army research programs. We also reviewed HHS and FDA regulations concerning

requirements for the protection of volunteers which apply to Army research experiments.

For information concerning the use of volunteers in Army research experiments conducted before 1975, we relied on the OIG report referred to in the footnote on page 1. In May 1984 we visited the U.S. Army Medical Research Institute of Chemical Defense, Edgewood Area, Aberdeen Proving Ground, Maryland, to determine actions taken by the Army to correct problems cited in the OIG report.

Because we did not perform a comprehensive review of current research experiments, we did not (1) determine whether the Army reviewed all research experiments for the protection of volunteers, (2) determine if all volunteers were fully informed of the experiments, and (3) review all individual research experiments to determine if Army procedures were being followed.

Our review was conducted in accordance with generally accepted government auditing standards.

PAST PROCEDURES FOR ARMY RESEARCH EXPERIMENTS

In 1976 the OIG reported on chemical agent experiments that used volunteers. This report discussed research experiments conducted by the Army from 1950 to 1975, which exposed volunteers to various chemical agents, including nerve agents and lysergic acid diethylamide (LSD).

In 1953, the Secretary of Defense established a policy authorizing each military service secretary to use volunteers in experimental research. A policy was necessary since essential research data could be obtained only by using humans. This policy provided that participation in experiments was subject to the conditions of voluntary consent. The volunteers were to be informed of the nature, duration, and purpose of the experiment, including any possible hazards.

The OIG found that despite clear guidelines concerning the necessity of obtaining informed consent, the intent of the policy was diluted and in some cases negated. In many cases, consent was relegated to simple, all-purpose volunteer agreements, signed by the volunteers, that did not provide detailed knowledge regarding the specific experiment or agent to which the volunteers would be exposed. The OIG concluded that, judged solely by the content of this agreement, the intent of the informed consent policy did not appear to be fulfilled.

The OIG, in reviewing the volunteer program at Edgewood Arsenal, Maryland, reported that the volunteers' official medical records did not contain information regarding the volunteers' participation in experiments. Nor was there any entry identifying the agents the volunteers received.

In June 1980 the Army began to correct this situation. The Army has now assembled individual case records for volunteers who participated in experiments at Edgewood Arsenal. The case records detail the history of volunteers' participation in individual experiments, including the identification of any agents the volunteers received. The Army is in the process of adding copies of these case records to the volunteers' medical records.

CURRENT ARMY RESEARCH EXPERIMENTS

In October 1974, HURO was established to insure uniform application of ethical standards for human research studies conducted within or sponsored by the Army. Proposed experiments are reviewed by committees (see pp. 5 and 6) to insure that the volunteers are protected and that procedures for obtaining fully informed consent have been initiated. The current Army procedures for the use of volunteers in research experiments conform with HHS and FDA regulations.

Volunteers in current research experiments conducted within USAMRDC are involved in the following:

--Research and development of vaccines.

--Research and development of antidotes and protectants against chemical and nerve agents.

--Research and development of drugs used to treat preexisting medical conditions.

--Research and development of drugs used to assist adaptation to environmental conditions.

--Research and development studies used to gain an understanding of the sociological, psychological, and physiological conditions of life and work in the Army.

Both civilian and military volunteers are used in these experiments.

REVIEW PROCEDURES FOR PROPOSED RESEARCH EXPERIMENTS

Proposed USAMRDC research experiments are usually reviewed by committees at two levels--the local command level and the Surgeon General level. Both of these review levels are concerned with protecting volunteers used in research experiments.

Human Use Committee review procedures

At the local command level, a Human Use Committee (HUC) reviews the proposed research experiments to assess the potential risks to the volunteers. As part of its review, the HUC determines if the risks to volunteers are

--minimized, by using procedures that are consistent with sound research design and do not unnecessarily expose volunteers to risk, and

--reasonable, in relation to anticipated benefits, if any, to volunteers and the importance of the knowledge that may be expected to result.

The HUC is composed of at least five members to provide a review of research activities commonly conducted within the local command. The HUC includes at least one member whose primary concerns are in nonscientific areas, for example, a lawyer. The members are qualified through experience and expertise to provide advice in safeguarding the rights and welfare of the volunteers.

Review procedures for the Human Subjects Research Review Board

After the proposed research experiment has been reviewed at the local level, a final review is made by the Army Surgeon General's Human Subjects Research Review Board (HSRRB), except when the HSRRB chairperson, rather than the Board, has been delegated approval authority by the Army Surgeon General.

For example, the chairperson has been delegated approval authority for minimal risk experiments. A minimal risk experiment is one in which the risks of harm anticipated in the proposed research are not greater than those encountered in ordinary life or during the performance of routine physical or physiological examinations or tests. In some experiments, volunteers are used only to provide blood samples or to engage in moderate exercise.

HSRRB consists of 12 members, whose function is to provide complete and adequate review of research activities. HSRRB may not consist entirely of members of one profession. In addition, HSRRB must include at least one member engaged in a nonscientific discipline, such as a member of the clergy, and at least one member not affiliated with the Department of the Army.

HSRRB reviews proposed research experiments to ensure that risks to volunteers are minimized and reasonable. After its review, HSRRB makes recommendations for final approval/disapproval or deferral of the research proposals to the Army Surgeon General.

For the 50 experiments we reviewed, copies of minutes of the HUC and HSRRB meetings had been prepared which showed that the reviews of proposed research experiments had been occurring as part of the research experiment approval process. We also discussed the review procedures with the Chairman of the HUC at the U.S. Army Institute of Surgical Research and with the Deputy Commander, U.S Army Medical Research Institute of Infectious Diseases. These officials reported that HUCs conducted reviews as a part of the approval process for proposed research experiments involving volunteers.

According to the Assistant Deputy Commander of USAMRDC, the Army plans to place greater responsibility on the HUCs to make final decisions regarding research proposals.

INFORMED CONSENT PROCEDURES

USAMRDC policy requires that prospective volunteers be fully informed of research experiments before consenting to participate. Included in the basic elements of informed consent are:

--An explanation of the purpose of the research.

--A description of the procedures to be followed.

--The identification of any experimental procedures.

--The expected duration of the volunteers' participation.

--A description of any foreseeable risks and/or benefits to the volunteers.

--A statement that participation in the experiment is voluntary and that the subjects may discontinue participation at any time.

Written informed consent must be obtained before volunteers participate in research experiments.

The principal investigator responsible for the experiment obtains informed consent by presenting volunteers with a written explanation of the experiment, allowing them to ask questions concerning the experiment, and then obtaining the volunteers' signature on volunteer agreements. This agreement is also witnessed by a third party. A copy of the volunteer agreement, including the written explanation of the experiment, is to be given to the volunteer. The original is retained by the local command administering the experiment.

The HURO records of current research experiments within USAMRDC include written explanations of experiments which are to be given to the volunteers. For the 104 experiments we reviewed, these explanations indicated that informed consent would be provided to volunteers regarding the experiment. These explanations met the basic elements of informed consent requirements as discussed above, including identification of any substances the volunteers would receive.

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As requested by your office, we have not obtained written comments on this report but have discussed our facts with officials responsible for the oversight of Army research experiments using volunteers. Also, as arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from its issue date. At that time we will send copies to interested parties and make copies available to others upon request.

Sincerely yours,

Richard L. Fogel
Director

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